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To: Exr. Phillip Gambel Fax: 703-746-5293

From: Raymond J. Lillie Date: 11/12/03

File #: 61750-221 Pages: 10 (including cover page)

Re: Request for Rehearing and Reconsideration, and date card. CC:

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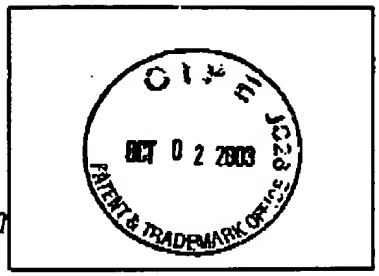
Applicant(s): Bazin, et al.

Serial No.: 09/056,072 Filed: April 7, 1998

Title (or mark): LO-CD2a Antibody and Uses Thereof for Inhibiting T-Cell Activation and Proliferation



DOCUMENTS ENCLOSED

- ☐ Application sheets: Descr.: _____ Drawing sheets: _____
- Claims _____ Abstract _____
- ☐ Formal ☐ Informal
- ☐ Declaration (executed _____)
- ☐ Assignment to _____
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- Atty.: BJL
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Examining Operations

Applicant(s): Bazin, et al.

Serial No: 09/056,072 Art Unit: 1644

Filed: April 7, 1998 Examiner: Gambel

Title: LO-CD2a Antibody and Uses Thereof for Inhibiting T-Cell Activation and Proliferation

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BOARD OF PATENT APPEALS AND INTERFERENCES

Attorney Docket No.: 61750-221

TRANSMITTAL LETTER

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

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Enclosed please find the following:

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Raymond J. Lillie 12/3/03

Raymond J. Lillie, Esq. Date

#196310 v1

Respectfully submitted,

Raymond J. Lillie

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Bazin, et al.
Serial No.:	09/056,072
Filed:	April 7, 1998
For:	LO-CD2a Antibody and Uses Thereof for Inhibiting T-Cell Activation and Proliferation
Group:	1644
Examiner:	Gambel

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

REQUEST FOR REHEARING AND RECONSIDERATION UNDER 37 CFR 1.197(b)

Sir:

Applicants respectfully request a rehearing and reconsideration under 37 CFR 1.197(b) with respect to the following rejections:

1. The rejection of Claims 30-32 and 35-37 under 35 U.S.C. 102(b) as anticipated by Xia.

2. The rejection of Claims 30-37 under 35 U.S.C. 103 as being unpatentable over Xia in view of either Queen or Newman, further in view of any one of Gückel, Bromberg, Hafler, Chavin, or Faustman.

A. Xia does not, necessarily or inherently, disclose Applicants' claimed antibody.

In affirming the rejections, the Board misapprehended or overlooked the point that the burden is upon the Examiner to show that Xia discloses all of the elements and

limitations of Applicants' claimed antibody, i.e., an antibody which binds to the same epitope on human lymphocyt s as the antibody produced by the cell line deposited as ATCC HB11423. (See Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1576, 18 U.S.P.Q.2d 1010 (C.A.F.C. 1991).) All of the elements, necessarily or inherently, must be present. The burden is upon the Examiner to show that by following the teachings of Xia, one must obtain an antibody that necessarily or inherently binds to the same epitope as the deposited antibody. (See Continental Can Co. v. Monsanto, 948 F.2d 1264, at 1268; 20 U.S.P.Q.2d 1746, at 1749.) The mere possibility or even the probability that one could obtain an antibody that binds to the same epitope as the deposited antibody by following the teachings of Xia is insufficient under the patent law to establish anticipation See Continental, 984 F.2d 1264, at 1269, 20 U.S.P.Q.2d, at 1749-1750, which held that:

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

Xia discloses a basic standard procedure for producing monoclonal antibodies. The burden is on the Examiner to show that by following such procedure, one obtains an antibody that necessarily or inherently binds to the same epitope as the deposited antibody.

Xia states that one of the antibodies recovered by the procedure is the LO-CD2a antibody; however, in order to anticipate the Examiner must demonstrate that if the Xia procedure is repeated, one skilled in the art necessarily would be able to obtain the claimed antibody.

Xia discloses a standard procedure that produces CD2 monoclonal anatibodies and, as recognized in the art (and as disclosed by Xia), such procedure would produce a myriad of CD2 antibodies.

Th re is nothing of record that would indicate that because LO-CD2a antibody was produced by Xia by such procedure that it necessarily would b produced again if the procedure were repeated.

In addition, if such an antibody were among the wide variety of antibodies produced by such a procedure, there is no evidence that one skilled in the art necessarily would be able to obtain such antibody from among the wide variety of other possible antibodies that may be produced by following the teachings of Xia.

The Examiner speculates that in repeating the procedure of Xia, an antibody as claimed would be produced and further speculates that the properties disclosed by Xia uniquely identify antibodies of the type claimed so that by testing for such properties, one skilled in the art necessarily would obtain the claimed antibody. Such speculation is not sufficient to meet the burden of proof required to establish that Xia anticipates Claims 30-32 and 35-37.

In contrast to the Examiner's speculation, Applicants have submitted evidence that the antibodies of Claims 30-32 and 35-37 would not be obtained necessarily by following the teachings of Xia.

Such evidence has been presented in the Declaration of Dr. Bierer. Dr. Bierer has testified that if one skilled in the art repeated the procedure disclosed by Xia, one skilled in the art would not be able to identify which of the antibodies was LO-CD2a or an antibody which binds to the same epitope as the deposited antibody. (Bierer Declaration, Paragraphs 5 and 6.) Thus, by following the teachings of Xia, one skilled in the art would not obtain necessarily or inherently an antibody which binds to the same epitope as the deposited antibody.

More particularly, all that Xia discloses is that LO-CD2a antibody has characteristics which are common to CD2 antibodies as a class. (See Bierer Declaration, Paragraph 7.) Such characteristics are general characteristics which are possessed by other CD2 antibodies and, therefore, screening antibodies for such

characteristics would not indicate whether or not a CD2 antibody were LO-CD2a, or whether or not an antibody is an antibody which binds to the same epitope as the deposited antibody. (Bierer Declaration, Paragraph 8.)

The data presented by Xia do not identify uniquely LO-CD2a or an antibody which binds to the same epitope as the deposited antibody. In order to identify or characterize LO-CD2a uniquely, one skilled in the art would need information with respect to the specific epitope to which LO-CD2a binds, and there is no such information in Xia. (Bierer Declaration, Paragraphs 9 and 10.) Because Xia lacks such information, Xia does not teach that the LO-CD2a antibody necessarily or inherently binds to the same epitope as the deposited antibody.

Although Xia, at Page 320, indicates that LO-CD2a binds to an epitope that is different from the epitope to which antibody D66 binds, Xia does not identify either epitope, and the information provided by Xia would not distinguish LO-CD2a from the plurality of other antibodies. (Bierer Declaration, Paragraph 11.)

The data shown in Table 1 and in Figures 1A and 1B of Xia merely define characteristics with respect to LO-CD2a which are characteristic of CD2 antibodies as a class and do not identify uniquely LO-CD2a or an antibody which binds to the same epitope as the deposited antibody. (Bierer Declaration, Paragraphs 12 and 13.)

Furthermore, the reactivity pattern shown in Figures 1A and 1B indicate that LO-CD2a is not different statistically from a known CD2 antibody OKT11. (Bierer Declaration, Paragraph 14.)

Although Table 4 of Xia indicates that LO-CD2a does not react with CEM cells whereas the known CD2 antibody T11 does react with CEM cells, it is well known in the art that other CD2 antibodies do not react with CEM cells and do react with MOLT4 cells, HPB-ALL cells and Jurkat cells, as does LO-CD2a. Thus, the characteristics of LO-CD2a shown in Table 4 of Xia do not identify LO-CD2a uniquely. (Bierer Declaration, Paragraph 16.)

The characteristics shown in Xia with respect to LO-CD2a are characteristics poss ssed in general by CD2 antibodies as a class, and some of such characteristics are similar to those of specific known CD2 antibodies. Such characteristics do not characterize LO-CD2a uniquely, and do not define the specific epitope to which LO-CD2a binds. Therefore, one skilled in the art who follows the teachings of Xia would not be able to characterize LO-CD2a uniquely and, therefore, would not necessarily or inherently produce an antibody which binds to the same epitope as the deposited antibody.

Xia merely teaches that LO-CD2a antibody is an antibody that binds to CD2. Although it may be possible that the LO-CD2a antibody of Xia binds to the same epitope as the deposited antibody, such possibility is insufficient to establish anticipation. The burden is upon the Examiner to show that the LO-CD2a antibody of Xia necessarily or inherently binds to the same epitope as the deposited antibody, and in light of the lack of information in Xia that would characterize or identify LO-CD2a uniquely and identify the epitope to which LO-CD2a binds, the Examiner clearly has failed to meet such burden. Therefore, Xia does not teach one skilled in the art, necessarily or inherently, as is required under the patent law for anticipation, to produce the claimed antibody, i.e., antibody which binds to the same epitope on human lymphocytes as the deposited antibody.

B. Xia does not enable one skilled in the art to produce the claimed antibody.

Because Xia discloses only that LO-CD2a antibody has characteristics which are common to CD2 antibodies as a class, those skilled in the art also would recognize that such characteristics do not enable one skilled in the art to identify uniquely LO-CD2a or an antibody which binds to the same epitope as the deposited antibody. Such characteristics are not suitable for distinguishing LO-CD2a from other antibodies produced by the general procedure disclosed by Xia, or to enable one skilled in the art to identify an antibody which binds to the same epitope as the deposited antibody.

Furthermore, the Examiner has provided no evidenc of record which indicates that the LO-CD2a antibody as described by Xia was mad availabl to the public prior to the effective filing date of the above-identified application. Thus, in light of the absence of teachings in Xia establish that one skilled in the art necessarily would obtain the antibodies of Claims 30-32 and 35-37, coupled with the lack of evidence of public availability of LO-CD2a prior to the effective filing date of the above-identified application, Xia clearly does not enable one skilled in the art to obtain necessarily an antibody which binds to the same epitope as the deposited antibody.

Thus, because following the teachings of Xia does not necessarily or inherently enable one to obtain LO-CD2a and other antibodies that bind to the same epitope as opposed to CD2 antibodies in general, Xia does not anticipate an antibody which binds to the same epitope as the deposited antibody. As stated previously, the possibility that the claimed antibody may be produced by following the teachings of Xia is not sufficient to establish anticipation. Because Xia does not enable one skilled in the art to obtain necessarily an antibody which binds to the same epitope as the deposited antibody, Xia cannot and does not anticipate an antibody which binds to the same epitope as the deposited antibody. (See Transclean Corp. v. Bridgewood Services, Inc., 290 F.3d 1364, 62 U.S.P.Q.2d 1865 (C.A.F.C. 2002); Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc., 246 F.3d 1368 (C.A.F.C. 2001), at 1374, 58 U.S.P.Q.2d 1508; Chester v. Miller, 906 F.2d 1574 (C.A.F.C. 1990), at 1577, 15 U.S.P.Q.2d 1333, at 1336; Akzo N.V. v. U.S. International Trade Commission, 808 F.2d 1471 (C.A.F.C. 1986), at 1479, 1 U.S.P.Q.2d 1241, at 1245; Paperless Accounting, Inc. v. Bay Area Rapid Transit System, 804 F.2d 659 (C.A.F.C. 1986), at 665, 231 U.S.P.Q. 649, at 653.)

C. Claims 30-37 are not obvious to one of ordinary skill in the art under 35 U.S.C. 103.

The obviousness rejection appears to have been sustained on the basis that a reference which anticipates the claimed invention also renders such invention obvious to one of ordinary skill in the art.

In light of the fact that no other independent reasoning has b n given, Applicants assert that Xia, which, for reasons including those stated hereinabove, does not anticipate Applicants' claimed antibody, also cannot be applied in asserting that Applicants' claimed antibody is obvious to one of ordinary skill in the art, and therefore Xia and the secondary references do not render Applicants' claimed antibody obvious to one of ordinary skill in the art under 35U.S.C.103

D. Conclusion

Thus, because Xia does not necessarily or inherently disclose the claimed antibody, and does not enable one skilled in the art to produce the claimed antibody, Xia does not meet the standards set under the patent law for anticipation or obviousness, and the Board's holdings that Xia negates the patentability of the claimed antibody are without merit.

For the above reasons and others, Xia does not negate the patentability of the claimed antibody, and it is therefore respectfully requested that the rejections of Claims 30-32 and 35-37 under 35 U.S.C. 102(b) and of Claims 30-37 under 35 U.S.C. 103 be reversed.

Respectfully submitted,

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